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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/524,432

09/09/2005

Stephen I. Madden

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EXAMINER

WEGERT, SANDRA L

ART UNIT

PAPER NUMBER

1647

MAIL DATE

DELIVERY MODE

06/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/524,432	Applicant(s) MADDEN ET AL.	
	Examiner SANDRA WEGERT	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 14-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/26/09</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Status of Application, Amendments, and/or Claims

The Amendments and Remarks, sent 26 March 2009 have been entered into the record. Claim 1 is amended. Claims 14-67 remain withdrawn. Claims 1-13 are under examination in the Instant Application.

Maintained/New Objections and Rejections

Claim Rejections- 35 USC § 102

The following are quotations of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The rejection of claims 1, 2 and 5-13 under 35 U.S.C. 102(a) for being anticipated by Lal, et al (2001, J. Natl. Cancer Inst., 93: 1337-1343) is *maintained*. Claims 1, 2 and 5-13 recite a method to aid in diagnosing glioma by detecting expression of "translocon-associated protein delta" (SEQ ID NO: 33). Lal, et al, also uses this gene and gene product to identify human glioblastoma (also called "glioma"). Lal, et al found a 2.3x increase in expression of translocon-associated protein delta by PCR and attribute the gene's expression to the hypoxia that is present

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in most solid tumors, suggesting that translocon-associated protein delta is a gene involved in the tumor's response to the lack of oxygen found in the center of solid tumors.

Applicants argue that "Lal et al., compares gene expression of a glioblastoma cell line under two types of conditions: hypoxic and normal oxygen levels" (Remarks, 26 March 2009, p. 8), contending that the method disclosed in Lal, et al is therefore different than the method recited in applicants' claims.

Applicants' arguments have been fully considered but they are not persuasive for the following reasons:

While it is true that the researchers in the Lal, et al reference focused their attention on genes expressed by tumors under hypoxic conditions, such as VEGF and translocon-associated protein delta, they did compare expression levels of the genes of interest to normal glial cells (see "NHA" or *normal human astrocytes* as the first column in Figure 2, B), meeting the limitations of the instant claims. In addition, the ratios expressed in Table 1 are derived from comparing the hypoxic gene transcripts to normal transcripts (see the footnote "\$" under Table 1).

Claim Rejections - 35 USC § 112, first paragraph - enablement.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 3 and 4 under 35 U.S.C. 112, first paragraph, for containing subject matter which is not enabled by the specification, is *maintained*. Applicants have not

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demonstrated that the ratios of expression between normal tissue and tumor tissue can reach 5 fold or ten fold, and that level of expression is not found in the literature. For example, Lal, et al, (2001, J. Natl. Cancer Inst., 93: 1337-1343, of record) described an expression ratio of approximately 2.3 times normal (as discussed above).

Applicants argue that Lal et al. teach a ratio based upon a comparison between two types of cancerous tissue: hypoxic and normal oxygen levels (Remarks, 26 March 2009, p. 9).

Applicants' arguments have been fully considered but they are not persuasive for the following reasons:

For the reasons outlined above, the comparison between expression in normal astrocytes and glioblastoma in Lal, et al is a valid comparison, and is the same method as that claimed in the instant application. Therefore, Lal, et al, can be used as a reference establishing non-enablement of claims 3 and 4.

Conclusion: Claims 1-13 are rejected for the reasons recited above.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Manjunath Rao, can be reached at (571) 272-0939.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

/SLW/

8 June 2009

/Bridget E Bunner/

Primary Examiner, Art Unit 1647